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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,299	10/27/2003	Peter M. Breining	021663-000110US	4186
20350	7590	04/06/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			MANAHAN, TODD E	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p align="center">10/695,299</p>	<p>Applicant(s)</p> <p align="center">BREINING ET AL.</p>	
	<p>Examiner</p> <p align="center">Todd E. Manahan</p>	<p>Art Unit</p> <p align="center">3732</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 and 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/08/03</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 25 and 60 are objected to because of the following informalities:

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25 merely reiterates that the substance comprises relaxin or an analog or mimetic thereof and thus does not place any further limitations upon base claim 24.

Claim 60 should depend from claim 56 instead of apparatus claim 54 and will be considered as such for examination purposes. Appropriate correction is required.

### ***Double Patenting***

Applicant is advised that should claim 23 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 13, 34, 61-64, 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 13, 34, and 69, use of the terminology "preferentially" renders the claim(s) indefinite since a broad range or limitation followed by linking terms (e.g., preferably, maybe, for instance, especially) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

In claims 61-64, 67, and 68, "the force" and "applying force" lack a prior antecedent.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 78 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 78 is directed to a naturally occurring article, relaxin. It has been held that a thing occurring in nature, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example. Ex parte Grayson, 51 USPQ 413 (Bd. App. 1941). Statements of intended use, i.e. "for use in the manufacture...." does not alter the article, relaxin in any way.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56,58, 70 and 78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nicozisis et al. (Reference 15 on PTO-1449).

Nicozisis et al disclose a method comprising the steps of administering relaxin to a living house, a mouse. Regarding claim 78, Nicozisis et al. disclose relaxin or an analog or mimic thereof. Statements of intended use, i.e. "for use in the manufacture...." Do not carry any patentable weight.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10-19, 22-29, 31-40,,57-64, 66-69, 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicozisis et al.

Nicozisis et al disclose use of Relaxin to affect the dentofacial sutural tissues in mice. On page 198, second and third paragraphs, "If mechanical manipulation of the sutures or periodontal ligament is an objective....Perhaps better demonstrative strains could be employed to show the effects of relaxin on the connective tissue of the craniofacial complex and the periodontium...relaxin's effect on the rate of tooth movement may be investigated along with the tendency for relapse once a tooth is moved or rotated." And on page 199, fifth paragraph, "There appears to be a potential application for relaxin as an adjunct to orthodontic therapy. Relaxin affects the collagen types synthesized within the craniofacial sutures and periodontium... It

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would also be beneficial to examine relaxin's effects on the network of elastin fibers that make up a small, yet important, portion of the gingival proteins." Also on page 199, sixth paragraph, Nicozisis et al disclose some possible applications of relaxin to include "enhancement of tooth movement and stability through reorganization of the PDL fibers" and "enhanced gingival remodeling following space closure". Therefore, based on the suggestion provided by Nicozisis et al, it would have been obvious to one skilled in the art at the time the invention was made to administer relaxin during orthodontic treatment. It is understood that orthodontic treatment involves applying a force to at least one tooth in order to move and/or rotate it into proper position. Regarding claims 8, 10, 11, et al. use of removable appliances, such as aligners, retainers and positioners, or wire and bracket appliances, in order to apply a force to a tooth and effect movement thereof is old and well known in the orthodontic field.

Claims 9, 30, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicozisis et al. as applied to claims 8, 29, and 64 above, and further in view of Kuo et al. (United States Patent No. 6,607,382).

Kuo et al. discloses a removable orthodontic appliance that includes a reservoir for administering a therapeutic substance concurrently with movement of the teeth. It would have been obvious to use a removable orthodontic appliance that includes a reservoir as taught by Kuo et al. with the method of repositioning teeth and applying relaxin suggested by Nicozisis et al. in order to apply the relaxin concurrently with tooth repositioning.

Claims 20, 21, 41, 42, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicozisis et al. as applied to claims 1, 22, and 56 above, and further in view of Korostoff et al. (United States Patent No. 4,153,060 cited by applicant).

Korostoff et al. disclose applying an electric current to the periodontal tissue to enhance bone growth and tooth movement. It would have been obvious to apply an electric current to the periodontal tissue as taught by Kuo et al. with the method of repositioning teeth and applying relaxin suggested by Nicozisis et al. in order to further enhance bone growth and tooth movement.

Claims 43-46, 48, 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al. in view of Nicozisis et al.

It would have been obvious to one skilled in the art to use relaxin as the therapeutic agent with the device of Kuo et al. in order to enhance tooth movement and stability as suggested by Nicozisis et al.

Claims 43, 47, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgio (United States Patent No. 6,322,360) in view of Nicozisis et al.

It would have been obvious to one skilled in the art to use relaxin as the therapeutic agent with the device of Burgio in order to enhance tooth movement and stability as suggested by Nicozisis et al.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd E. Manahan whose telephone number is 703 308-2695. The examiner can normally be reached on Mon-Fri.

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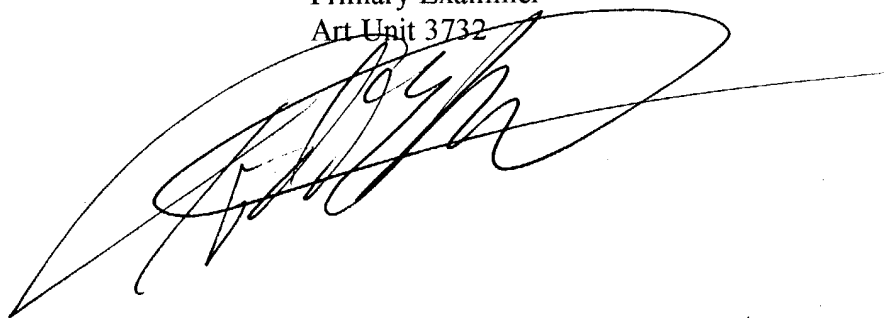
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 703 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Todd E. Manahan  
Primary Examiner  
Art Unit 3732

T.E. Manahan

1 April 2004

A large, stylized handwritten signature in black ink, likely belonging to Todd E. Manahan, is written over the printed name and title.